

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<b>In re the Application of:</b>	)	
	)	<b>Group Art Unit:</b> 3731
<b>Clifford Teoh, et al</b>	)	
	)	<b>Confirmation No.:</b> 9672
<b>Serial No.: 10/631,928</b>	)	
	)	<b>Examiner:</b> Vi X. Nguyen
<b>Filed:</b> July 31, 2003	)	
	)	
<b>For:</b> EXPANDABLE BODY CAVITY	)	
LINER DEVICE	)	

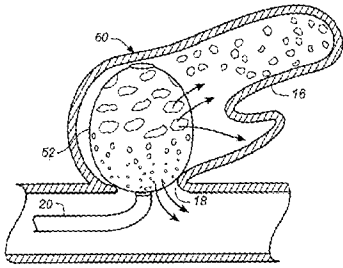
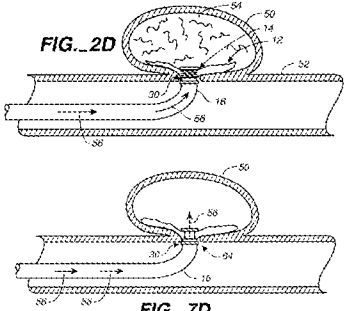
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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Appellants respectfully request a pre-appeal brief conference. No amendments are being filed with this request. Therefore, claims 1, 2, 5-7, 9, 10 and 13-16, 18-19 and 21-23 remain pending in this application, and stand rejected under 35 U.S.C. §102(e), as allegedly being anticipated by U.S. Patent No. 6,454,780 (“Wallace”).

According to the Final Office Action (“FOA”) (in pages 2-4 under **35 U.S.C. §102**) Wallace discloses a method for occluding an aneurysm having the acts of independent claim 1, and further discloses an assembly for treating an aneurysm having the elements of independent claim 15. However, Appellants respectfully submit that the references made to Wallace in the FOA do not, in fact, teach the acts and elements recited by claims 1 and 15 of the present application.

Regarding **claim 1**, the below table compares and illustrates the acts of the claimed method versus the acts disclosed in Wallace.

US Application 10/631,928	Wallace USPN 6,454,780
<p><b>Claim 1:</b> A method of occluding an aneurysm, the aneurysm having a neck and a sac, the method comprises the acts of:</p> <p>delivering a liner into the aneurysm, the liner having a proximal portion and a distal portion, where the distal portion of the liner is more permeable than the proximal portion of the liner,</p> <p><b>allowing</b> the liner to <b>expand</b> within the aneurysm to define a <b>substantially spherical interior volume</b> within the aneurysm, so that the proximal portion of the liner extends across the aneurysm neck and the distal portion of the liner is positioned within the aneurysm sac, and</p> <p><b>introducing</b> embolics through an opening in the proximal portion of the liner <i>into the substantially spherical interior volume of the liner</i>, wherein the distal portion of the liner allows preferential permeation of the embolics from the substantially spherical liner interior volume into the sac of the aneurysm.</p>	<p>Wallace discloses a method for occlusion the neck portion of an aneurysm by:</p> <p>delivering a collapsible neck bridge into an aneurysm in a deployed expanded state,</p> <p><b>constricting and collapsing</b> the neck bridge at the neck of the aneurysm using an actuation mechanism, and</p> <p>introducing an embolic agent “along the path demonstrated by arrows 56, through elongated delivery member, through joint 30 (a detachment point) <b>through a conduit formed through a retracted device 64</b> in to the aneurysm 50” (Col 12, lines 1-8, Fig. 7D) (Emphasis added).</p>
 <p><b>FIG. 4</b></p>	 <p><b>FIG. 2D</b></p> <p><b>FIG. 7D</b></p>

Appellants respectfully submit that the FOA errors in making the anticipation rejection of claim 1, since the act of introducing the embolic agents disclosed in Wallace is performed **after** the act of collapsing the neck bridge that forms a flattened disk (Col. 3, lines 2-13, Col. 8, lines 5-11, Figs. 2D, 7D). Thus, the acts of first collapsing the neck bridge, and thereafter introducing an embolic material through a conduit formed by the collapsed device taught by Wallace are, in fact, **opposite** the acts recited by claim 1 of the present application.

Appellants respectfully point out that the FOA is in error when stating (on pages 2 and 3):

the method comprising: delivering a liner (64 and 66 are made of a liner) into the aneurysm, ...(see annotated below, fig. 7a...)...allowing the liner to expand to form a substantially spherical interior volume within the aneurysm... *(it is noted that the aneurysm device 64/66 comprises a body that has a shape of a sphere which embolics can go through an opening in the proximal portion of the liner into the substantially spherical interior volume of the liner).* (Emphasis added.)

The FOA is also in error when stating that elements 64 and 66 of Wallace are “made of a liner.” In fact, Wallace discloses that element 64 is the “collapsible aneurysm obstructive device” of Fig. 7A (Col. 11, line 16, to Col.12, line 8), and element 66 is the “woven material” that covers the struts 68 of the proximal portion of the device 64 (Col. 11, lines 33-37). Thus, only element 66 could be considered the “liner” in Wallace.

Further, the FOA erred in referring to Fig. 7A of Wallace in the rejection of the method of claim 1, since Wallace does **not** disclose or suggest a method of introducing embolics into the device of Fig. 7A, when the device is deployed having the same configuration shown in Fig. 7A. Although, Fig. 7A of Wallace depicts a neck bridge having an “inverted parachute configuration,” Wallace actually teaches the acts of **constricting the delivered device** into a deployed configuration (see Fig. 7D above), and thereafter **introducing embolics through a conduit** formed by the retracted device or an actuation mechanism. (Col 12, lines 7-8). Thus, Wallace does not disclose or suggest a method of introducing embolics through an opening in the proximal portion of the liner into a substantially spherical interior volume of the liner wherein the distal portion of the liner allows preferential permeation of the embolics from the substantially spherical liner interior volume into the sac of the aneurysm, as recited by claim 1.

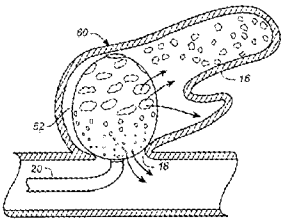
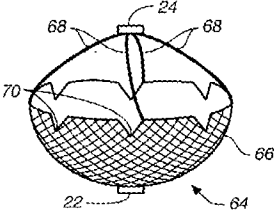
Appellants respectfully point out that the FOA erred by stating in pages 5 that:

... it is noted that annotated below Fig. 7a discloses such embolics introduced through an opening in the proximal portion of the liner into a substantially spherical interior volume of the liner...

In particular, the FOA is erroneously confusing the acts of the method claim 1 with the elements of the device of Fig. 7A of Wallace. Although Fig. 7A of Wallace depicts a neck bridge having an “inverted parachute configuration,” the **acts** of introducing embolics into the neck bridge and the aneurysm sac are performed **after** the acts of **constricting and flattening out the device**. Thus, the claimed act of preferential permeation of the embolics from a liner substantially spherical interior volume into the aneurysm is **not possible** in Wallace, since the device of Wallace is constricted before introduction of embolics, and cannot form a substantially spherical interior volume where the distal portion is more permeable than the proximal portion. Appellants respectfully point out that the constricted and flattened out neck bridge of Wallace forms a conduit (see above) through where the embolics are introduced into the aneurysm, and

there is no disclosure or suggestion in Wallace that a portion of the conduit is more permeable than other portion.

Regarding **claim 15**, the below table compares and illustrates the elements of the claimed assembly versus the elements of the assembly disclosed in Wallace.

US Application 10/631,928	Wallace USPN 6,454,780
<p><b>Claim 15:</b> An assembly for treating an aneurysm, the aneurysm having a neck and a sac, comprising:</p> <p>a liner having a proximal portion and a distal portion, and defining a substantially spherical interior volume within the proximal and distal portions; wherein the distal portion has <b>perforations</b> sized to permeate embolics and is more permeable than the proximal portion, such that the distal portion preferentially permeates embolics from the substantially spherical interior volume into the aneurysm sac, and</p> <p>an elongated delivery member releasably connected to the liner.</p>	<p>In contrast, Wallace discloses a neck bridge device having a “light weight...yet still forms a solid, potentially two-layered” liner (Col. 6, lines 58-66, Figs. 1A-B, 2A-E, 3) and a neck bridge device having an “inverted parachute configuration” where “<b>struts 68 are utilized rather than additional material 66</b> so as to eliminate some bulk of the device 64.” (Col. 11, lines 15-17, 33-35, Fig. 7A) (Emphasis added).</p> <p>The neck bridge device of Wallace is either covered by a solid liner, or has a liner <b>only</b> in the proximal portion of the device with the <b>distal portion struts free of any covering or liner</b>.</p>
 <p style="text-align: center;"><b>FIG. 4</b></p>	 <p style="text-align: center;"><b>FIG. 7A</b></p>

Appellants respectfully point out that the FOA errors when stating (on page 4):

*the distal portion has perforations sized to permeate embolics. .. (it is noted that the distal portion has larger aperture which is inherently more permeable than the proximal portion...).* (Emphasis added.)

In particular, the FOA erred in stating the distal portion of the device of Fig. 7A of Wallace has “perforations”. In fact, Wallace **expressly** discloses that the distal end of the device of Fig. 7A is free of any covering or liner 66 and only has bare struts 68 to “eliminate the bulk of the device” (Col. 11, lines 15-17, 33-35, Fig. 7A). Thus, it is not possible for the device of Wallace to have “perforations” on a distal portion liner that does not exist. Therefore, the neck bridge device of Wallace does not disclose or suggest a distal portion liner having **perforations** sized to permeate embolics and that is more permeable than the proximal portion of the liner, as recited by claim 15.

Appellants respectfully point out that neither the “aperture” nor the space between the struts in Wallace are “inherent perforations.” Inherency relates to existing parts or consequences as a natural result of an explicit disclosure (Schering, 339 F. 3d at 1379). Inherency, however, may not be established by probabilities or possibilities (MPEP 2163.07). Appellants submit that the FOA is in error in finding that Wallace inherently discloses a liner distal portion having perforations sized to permeate embolics and is more permeable than the proximal portion, since Wallace explicitly discloses the exact opposite. Additionally, it is not a “natural result” of bare struts to be considered as a liner with perforations.

Additionally, Appellants wish to point out that the FOA erred in considering that the perforations of the distal portion of the liner “merely adds functional limitation” (page 6). Instead, claim 15 recites that the distal portion of the liner **has** perforations, which recites an element of the liner distal portion.

For at least the foregoing reasons, Appellants respectfully submit that the FOA has not set forth a prima facie case that independent claims 1 and 15, along with their respective dependent claims 2, 5-7, 9, 10, 13-14, 16, 18-19 and 21-23, are anticipated over Wallace.

Respectfully submitted,

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